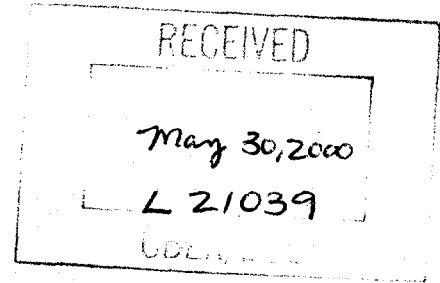


BONFILS BLOOD CENTER

Colorado's Community Blood Center



May 26, 2000

Jay S. Epstein, MD
Director
Office of Blood Research and Review (HFM-3000)
Center for Biologics Evaluation and Research
1401 Rockville Pike
Room 400N
Rockville, MD 20852-1448



Dear Doctor Epstein:

I am writing to request that you exempt blood derivatives (as you have blood products) from the final rule of the Prescription Drug Marketing Act (PDMA), which takes effect on December 4, 2000, so that not-for-profit regional blood centers can remain both a distributor of blood derivatives as well as serve as a health care entity. Currently in the state of Colorado, both patients and healthcare facilities benefit from the blood center serving in both capacities because cost is minimized due to bulk purchasing and centralized storage of the product. A wider variety and assay levels of the products is locally available to treat Colorado patients, outdate is minimized through stock rotation, and redundancy of required storage equipment is eliminated.

Bonfils Blood Center is an FDA licensed blood establishment whose mission is to meet the comprehensive transfusion needs of Colorado and surrounding areas. This currently includes:

A. Full service blood center which:

- 1) Is licensed to draw, test, prepare, store, and ship 19 different blood products drawn at 9 different locations. These number of products more than double when the unlicensed products are included.
- 2) Operates a full service cord blood stem cell bank that collects, processes, and distributes stem cells for the treatment of a variety of malignancies and is affiliated with the National Marrow Donor Program.
- 3) Recruits bone marrow donors for the Colorado Marrow Donor program.
- 4) Performs both therapeutic whole blood collections and apheresis procedures (which include red cell exchange transfusions for sickle cell anemia; plasma exchange transfusions; immunoadsorptions to treat various neurologic, hematologic, and autoimmune diseases; platelet and white cell depletions).

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- 5) Operates a comprehensive donor testing laboratory service (includes a NAT testing laboratory for HCV and HIV) which performs donor testing for both our donors and several other donor collection centers.
 - 6) Operates a transfusion service that provides compatibility testing services to home and outpatient transfusion services, and to hospitals throughout the region. This service performs over 28,000 crossmatches, and types and antibody screens annually.
 - 7) Operates an AABB certified reference laboratory which resolves complex serologic testing issues so that the most appropriate blood products can be provided to the patient.
 - 8) Maintains an inventory of frozen red blood cells units with rare or unusual phenotypes which is shared nationally for patients with complex serologic problems.
 - 9) Provides blood and blood products to over 90 facilities both within and outside the state of Colorado.
 - 10) Provides recovered plasma to fractionators under a short supply agreement for the preparation of a variety of products including blood derivatives.
- B. Source plasma program which is currently being licensed to provide the raw material for Rh Immune Globulin and serologic reagents.
- C. An inventory of red blood cells which are the raw material for serologic testing reagents.
- D. A molecular/genetic testing laboratory which determines compatibility for organ and tissue transplantation.
- E. And, Bonfils currently has a wholesale drug distributor license from the State of Colorado for the distribution of blood derivatives such as solvent detergent plasma, factor VIII, factor IX, antithrombin III, varasella zoster, and antithrombocyte globulin. We routinely keep 3-4 different kinds for factor VIII and 3 kinds of factor IX, each with various assay levels, for patients in the region.

We feel that the distribution of blood derivatives is an integral part of meeting the transfusion needs of our area. These products are expensive and are infrequently used but are critical to survival when needed. They have strict storage requirements which are similar to the blood products that we prepare and distribute and they have variable expiration dates. They are routinely requested through the transfusing facility's blood banks.

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By centralizing the distribution of these products, we can provide a wider variety of products and variable assay levels to the region. We utilize the distribution system that is currently used to distribute blood products (minimizing cost and eliminating the need to establish a separate system), use the existing storage facilities, minimize product outdate/wastage because each facility does not have to maintain an inventory of the infrequently used products, provide a centralized location to obtain products from a variety of manufacturers with single call, provide a potential for volume purchasing discounts, and provide medical experts who can be consulted on product usage. All of this is provided in a GMP regulated environment.

For these reasons and the concern of increasing pharmaceutical costs at the hospitals, we respectfully request that blood derivatives be exempted from the final rule of the Prescription Drug Marketing Act (PDMA) which takes effect on December 4, 2000.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Puckett', with a large, stylized initial 'T'.

Thomas C. Puckett
Chief Operating Officer
And Administrator

TCP/MW/bec